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Original Research

A Randomized Controlled Trial to Evaluate the Veterans' In-home Program for Military Veterans With Traumatic Brain Injury and Their Families: Report on Impact for Family Members

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Abstract

Background: Traumatic brain injury (TBI) creates many challenges for families as well as for patients. Few intervention studies have considered both the needs of the person with TBI and his or her family and included both in the intervention process. To address this gap, we designed an innovative intervention for veterans with TBI and families—the Veterans' In-home Program (VIP)—targeting veterans' environment, delivered in veterans' homes, and involving their families.

Objectives: To determine whether the VIP is more effective than standard outpatient clinic care in improving family members' well-being in 3 domains (depressive symptoms, burden, and satisfaction) and to assess its acceptability to family members.

Design: In this randomized controlled trial, 81 dyads (veteran/family member) were randomly assigned to VIP or an enhanced usual care control condition. Randomization occurred after the baseline interview. Follow-up interviews occurred 3-4 months after baseline, and the interviewer was blinded to group assignment.

Setting: Interviews and intervention sessions were conducted in veterans' homes or by telephone.

Participants: A total of 81 veterans with TBI recruited from a Veterans Affairs (VA) polytrauma program and a key family member for each participated. Of the 81 family members, 63 completed the follow-up interview.

Intervention: The VIP, guided by the person—environment fit model, consisted of 6 home visits and 2 telephone calls delivered by occupational therapists over a 3- to 4-month period. Family members were invited to participate in the 6 home sessions.

Main Outcome Measures: Family member well-being was operationally defined as depressive symptomatology, caregiver burden, and caregiver satisfaction 3-4 months after baseline. Acceptability was operationally defined through 3 indicators.

Results: Family members in the VIP showed significantly lower depressive symptom scores and lower burden scores when compared to controls at follow-up. Satisfaction with caregiving did not differ between groups. Family members' acceptance of the intervention was high.

Conclusions: VIP represents the first evidence-based intervention that considers both the veteran with TBI and the family. VIP had a significant impact on family member well-being and thus addresses a large gap in previous research and services for families of veterans with TBI.

Introduction

Traumatic brain injury (TBI), a major public health problem in civilian and military populations, affects about 5.3 million persons in the U.S. [1] and up to 23% of U.S. soldiers returning from the Iraq and Afghanistan combat theaters [2,3]. Although TBIs are characterized on a continuum of severity from mild to severe, most are mild, representing 82% of military TBI cases [4] and 80% of civilian TBIs [5]. Sequelae of TBI are diverse and may include impairments in cognitive, physical, emotional, social, and behavioral functioning [6-14]. Recent literature indicates that persons with TBI, even mild TBI, may experience long-term emotional and physical health consequences [4,15].

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Given the possible sequelae from TBI, it is not surprising that TBIs can have a profound impact on family members and the family as a whole. Numerous studies have documented challenging outcomes that family members commonly experience: significant levels of depression, stress, and anxiety [16-20]; caregiver burden [17,21,22]; social isolation [22-25]; decreased quality of life [26]; financial difficulties [20]; and worse perceived health [27]. Caregiver depression and burden are the most common psychosocial problems reported by family caregivers [28]. Previous research has also described the impact of TBI on the family system: increased family dysfunction [17,29,30], family conflict [31], communication problems [32], and marital problems [33]. Behavioral and emotional changes are the most distressing TBI-related symptoms for family members [29]. With these changes, family members may experience an ambiguous loss—their loved one is not dead but is a very different person to them [34,35].

Although extensive literature describes negative family sequelae, little research has focused on positive aspects of caregiving, such as satisfaction, affirmation, and meaning derived from taking care of a loved one. Evidence suggests that some family members of persons with TBI report positive feelings and experiences, such as satisfaction, with caring for a relative with TBI [21,36,37]. Such positive aspects of caregiving echo experiences of caregivers of persons with dementia, frailty, stroke, and schizophrenia [38-43]. Consideration of both positive and negative outcomes in families of persons with TBI is warranted to capture the complexity of families' experiences [37]. Therefore, the outcomes for the present study included family member satisfaction, depressive symptoms, and burden.

Recognizing TBI as a family affair, emerging literature has emphasized family needs and called for interventions that address both patient and family needs [44-47]. Families are the primary supports for persons with TBI and can be critical to the success of rehabilitation [48]. As such, they need education about TBI and a clear understanding of their relative's condition, as well as emotional support and assistance in solving problems posed by their relative's care [48-52]. However, few studies have evaluated family-inclusive interventions using rigorous methodology [44,53]. In their 2007 review, Boschen et al [44] identified only 4 intervention studies designed to reduce caregiver distress, concluding that no evidence exists to support the usefulness of any single psychosocial intervention for family caregivers of persons with TBI.

Since the review by Boschen et al [44], few rigorous intervention studies have targeted both the person with TBI and a family member or only the family member. In a randomized controlled trial (RCT), Rivera et al [52] tested a problem-solving training (PST) program, guided by cognitive behavioral therapy, with family caregivers of persons with TBI, delivered through 4 in-home sessions and 8 telephone sessions over 1 year. Family caregivers in the PST group showed significant decreases in depression, health complaints, and dysfunctional problem-solving style but no perceived decrease in burden. Backhaus et al [54], in an RCT with patients with TBI and their families, tested the effectiveness of a 12-session cognitive-behavioral treatment group providing psychoeducation, supportive psychotherapy, stress management, and problem-solving strategies. Intervention participants (patients and family members combined as 1 group) showed significantly improved perceived self-efficacy immediately following treatment and at 3-month follow-up, yet no decrease in psychological distress at either time. Another RCT with patients and family members or significant others [55] found benefits of peer mentoring, namely, increased behavioral control, positive coping, and quality of life for patients and improved community reintegration for families. In a fourth RCT, Carnevale et al [56] tested the impact of a behavioral management program in the home on persons with acquired brain injury and family caregivers. Those with brain injury showed significant reductions in problematic behaviors, but caregivers had no significant improvement in perceived stress or burden.

In a noncontrolled study, Kreutzer et al [16] evaluated the impact of the Brain Injury Family Intervention for TBI survivors and families. Delivered through five 2-hour sessions in a clinic, the intervention consisted of education concerning TBI, coping with loss, stress management, goal setting, and problem solving. At posttreatment and 3-month follow-up, family members reported significant increases from pretreatment in met needs in the areas of health information, professional support, and care involvement, but not in emotional, instrumental, or community support. No significant differences were noted in psychological distress, family functioning, or life satisfaction from baseline. In another noncontrolled study [57] testing multiple family group therapy, both patient and family participants showed significant benefits, with family members reporting reduced caregiver burden.

Among the previously cited interventions with family members, most were conducted in clinic/hospital settings, and none focused on home environmental approaches based on an explicit and well-developed model. Furthermore, past intervention research around TBI as a whole has been limited by the following: an absence of interventions in the home, where the sequelae of TBI manifest; lack of a family focus or inclusion of family members in the intervention; and a narrow medical restorative approach that centers primarily upon restoring deficits within the person with TBI rather than on modifying the environment. Past research has also lacked rigorous methodology, with few studies controlling for improvements that may occur over time [44,58].

The Veterans' In-home Program (VIP) [58] addresses these limitations. VIP is a service for veterans with TBI that is delivered by occupational therapists in veterans' homes and with the engagement of family members, who are the primary supports for persons with TBI and also often the hidden victims. The rationale for using the home environment as a therapeutic modality is based upon the person—environment fit model, which posits that as the person's competency declines, an unchanging physical and social environment poses significant demands (called "environmental press") on the person with TBI that may result in maladaptive behavior and negative affect [58-60]. Adjusting and simplifying aspects of the home environment to match reduced competency (a better person—environment fit) can minimize excess disability, promote adaptive behavior, and improve affect. Strategies learned for environmental modifications can be applied to other settings [59,61-65].

Moreover, VIP's environmental approach should yield benefits for family members. It offers family caregivers a set of skills and strategies that lowers environmental press for the veteran with TBI and helps caregivers develop a supportive environment promoting veteran functioning [59,61-65]. Because this approach provides caregivers with practical skills to exert control over difficult situations, it targets caregiver distress and coping in managing day-to-day TBI-related problems. Therefore, we anticipated that the VIP approach would affect the caregiver's own level of depression, perceived burden, and satisfaction with caregiving.

Delivery of the VIP in the home facilitates family involvement. It also provides opportunities to interact with veterans and family members in their natural environment, observe their functioning and roles, assess the home environment and the person—environment fit, and identify relational issues less obvious in a clinic setting [58].

With its 2-group RCT design, the VIP study overcomes methodological limitations of earlier studies that used pre—posttest designs without controls. Furthermore, VIP extends environmental and psychosocial approaches used to promote the person—environment fit with other populations that share some clinical characteristics with TBI patients [60-65].

The purpose of this study was to evaluate VIP's effects on family members' well-being, specifically, their depressive symptoms, caregiver burden, and satisfaction with caregiving, and its acceptability to them. Winter et al [58] reported on the efficacy and acceptability of VIP for veterans with TBI, demonstrating benefits for greater community reintegration and lower difficulty managing the most difficult TBI-related problems identified by veterans themselves.

Methods

Design

The design was a 2-group RTC with 81 dyads. Participants were veterans with TBI and a family member or partner of each. Both veterans and family members were interviewed in their homes at baseline and later randomly assigned to VIP or the control condition. Randomization, achieved using random permuted blocks to control for possible changes over time in the subject mix, was done by a biostatistician independent of the study. A principal investigator randomized each dyad within 48 hours of the baseline interview. Those randomized to treatment were offered the VIP intervention, and they continued to receive their usual clinic care. Veterans in the control condition received the usual clinic care plus 2 telephone calls during the study period (an enhanced usual-care control condition). Participants in both conditions received a follow-up interview in the home or by telephone 3-4 months after the baseline interview, conducted by a master's-prepared social worker blinded to group assignment. With the use of home interviews and home intervention, treatment contamination between groups was avoided.

An intent-to-treat model was followed. Data from all participants were included in analyses regardless of their continued participation or level of participation in the intervention.

Setting and Sample

The study was approved by the Institutional Review Board of the Corporal Michael J. Crescenz VA Medical Center. Study participants included 81 dyads, comprising 81 veterans with TBI and for each one a family member selected by the veteran. The sample size was originally determined by powering for a medium-to-large effect size (0.25 to 0.4) and anticipating a possible attrition rate of 20%. Veterans were recruited from a VA outpatient polytrauma program. All veterans enrolled in the outpatient polytrauma program at the study site have a TBI diagnosis. Other typical comorbidities include musculoskeletal problems, posttraumatic stress disorder (PTSD), depression, pain disorders, and visual problems. All veterans in our sample, even those from previous combat theaters before Iraq and Afghanistan, had received a recent evaluation and diagnosis of TBI within the polytrauma program.

A letter of invitation was mailed to eligible veterans, followed by a telephone call that explained the study in more detail and confirmed the veteran's willingness and study eligibility. Inclusion criteria included the following: residence in the Philadelphia metropolitan region; receipt of TBI diagnosis as outpatients at the polytrauma program; postdeployment from the Vietnam War era to the present; ability to speak English; and having a family member or partner living with him or her or living within close proximity (within 30 minutes' transportation time) who was willing to take part in the study. The family member was identified by the veteran as actively involved in his or her life. The sole exclusion criterion was a veteran being at high risk for violence, as assessed by clinicians in the polytrauma program.

The Consolidated Standards of Reporting Trials (CONSORT) chart (Figure 1) displays the numbers of family members recruited, enrolled, and randomized to each treatment condition, as well as the number who received the intervention, were interviewed at follow-up, or were lost to follow-up, and the reasons for loss.

VIP Intervention

VIP is designed to optimize the veteran's daily functioning through the introduction of the following: compensatory strategies to enhance cognitive functioning; emotion-regulation strategies to manage behavioral and interpersonal difficulties; and home environment modifications (eg, equipment) to support functioning [58]. These intervention strategies target modifiable factors in the environment (eg, physical attributes of home, environmental prompts how tasks are performed, family routines, and family communication styles) to reduce environmental press, and are developed in the home with family knowledge and support. Compared to strategies learned in a clinic setting, such interventions should generalize more easily to home situations and the community [66].

The role of family members in VIP encompasses the following: using their insights and perspectives to identify TBI-related problems; enlisting their support and cooperation in implementing and reinforcing intervention strategies, to maintain use over time and apply to new situations; receiving education about TBI generally and how TBI is affecting their family member specifically; and receiving support through provision of coping and problem-solving strategies. The involvement of family in the present study is therefore two-fold: Family education and support is part of the intervention (to facilitate better outcomes for veterans), and VIP also targets the well-being of family members as a desired outcome.

VIP involved up to 8 contacts: 6 in-home visits with a licensed occupational therapist (OT) of 1-2 hours duration each and 2 telephone contacts with the OT over a 4-month period. The OTs were master's prepared and licensed, with clinical and research experience in patient and family interventions based on the person—environment model. Four months was viewed as

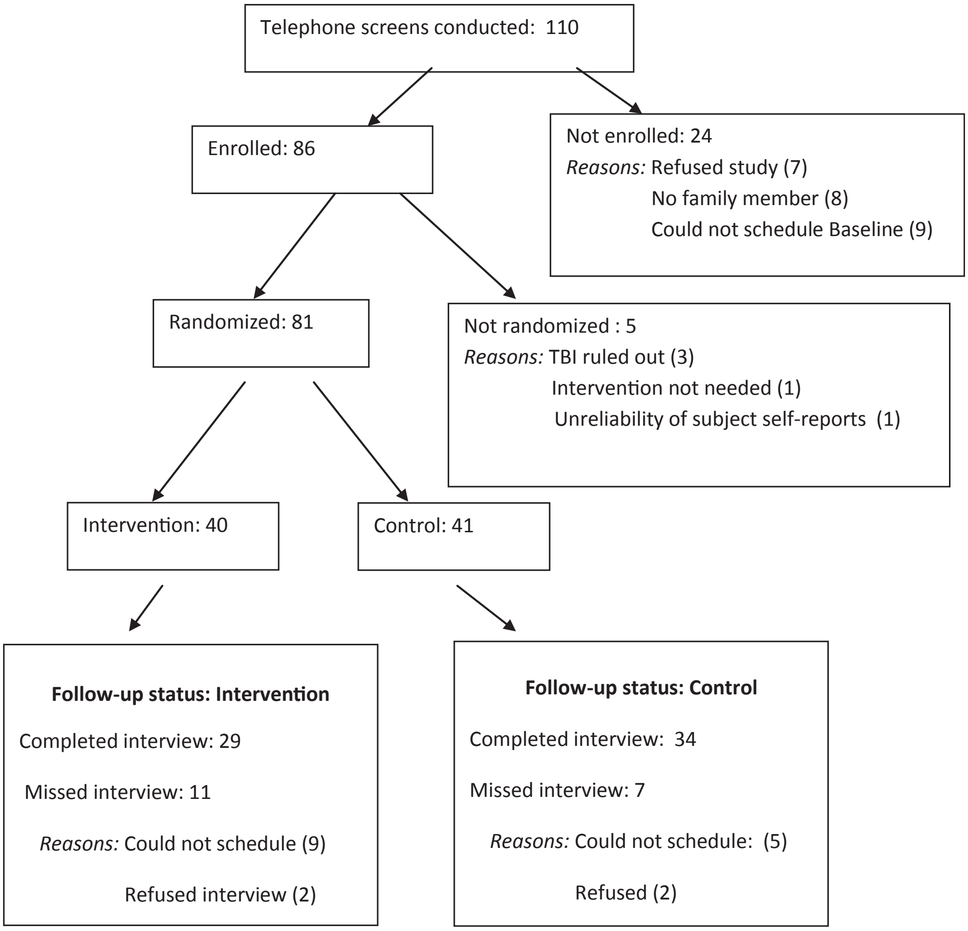
Telephone screens conducted: 110
Enrolled: 86
Not enrolled: 24
Reasons: Refused study (7)
No family member (8)
Could not schedule Baseline (9)
Randomized: 81
Not randomized : 5
Reasons: TBI ruled out (3)
Intervention not needed (1)
Unreliability of subject self-reports (1)
Intervention: 40
Control: 41
Follow-up status: Intervention
Completed interview: 29
Missed interview: 11
Reasons: Could not schedule (9)
Refused interview (2)
Follow-up status: Control
Completed interview: 34
Missed interview: 7
Reasons: Could not schedule: (5)
Refused (2)

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram for family members of veterans with traumatic brain injury (TBI).

the optimal time to establish rapport and collaboration and to build skills [64,65]. Family members were invited to take part in the 6 home sessions.

The intervention consisted of 3 phases. In phase I (assessment; contacts 1 and 2), the OT met with the veteran and family member together, unless otherwise requested, to elicit their concerns, to discuss intervention goals, to administer assessments of cognitive functioning and occupational performance to the veteran [67-70], and to inspect the home for environmental supports and barriers. In phase II (contacts 3-7), the problems that the veteran sought to address (eg, poor organization, poor memory, emotional lability) were identified through standardized assessment, and after individualized analysis, the results were discussed with the veteran and family member when available. For each identified problem area, a written Action Plan was developed that documented the problem, targeted goals, and described specific strategies (eg, memory-enhancing devices, mood regulation strategies), which was subsequently referred to and updated throughout the intervention. If home modification, equipment, or assistive devices were needed (eg, memory aids), the interventionist arranged for their delivery, installation, and training in their use through the polytrauma program and medical center's prosthetics department. In phase III (closure, final in-home visit), strategies were reviewed, practiced, and applied to emerging and potential future concerns [58]. Table 1 presents detailed descriptions of each session, including activities with family members that were part of the intervention. A more detailed description of the intervention, along with examples of how intervention strategies address complex interrelated TBI problems, are reported elsewhere [58]. Family members were also encouraged to learn about these strategies and to reinforce the veterans' application over time. For example, the interventionists coached some veterans to use iPhone apps for managing appointments, setting reminder alarms, and recording lists and important information; family members reminded veterans to use this strategy and also communicated with the veteran through these apps. Modifications to the home, such as creating an accessible, organized control station for the veteran's personal items, were recommended by the interventionist and reinforced by the family member.

To ensure intervention fidelity, debriefing meetings were conducted with interventionists and principal investigators approximately every 3 weeks. In addition, 8% of intervention sessions were observed by 1 of the principal investigators.

Control Condition

The control condition consisted of standard outpatient clinic-based TBI care offered to the veteran by the multidisciplinary care team of the polytrauma program, supplemented by 2-3 telephone calls provided by the research team. The calls, averaging 14.3 minutes (standard deviation [SD] = 6.85) in duration, were conducted primarily with the veterans and with family members (separately) when available. The calls focused on the general well-being of the veteran and family, any changes that had occurred, and reminders about follow-up interviews [64,65]. Of note, veterans and family members in both the intervention and control conditions received usual outpatient care from the polytrauma program. Family involvement in usual care is very limited, as family members rarely attend veterans' regular clinic visits. There is no formal or systematic involvement of family members in outpatient visits; occasionally, clinicians invite family members to veterans' outpatient appointments.

Measures

At both baseline and follow-up, we collected data for caregiver burden, caregiver satisfaction, depressive symptoms, and other measures. We also administered to veterans a battery of measures, described elsewhere [58].

Family Member Characteristics

Sociodemographic data from the family member included age, gender, race, Hispanic ethnicity, years of education, marital status, years married, number of children, household size, household composition, and financial difficulty ("How difficult is it to pay for basics like food, housing, and medical care?" [71]). The response format for the financial question was a 4-point Likert scale, from 0 (not at all) to 3 (very).

Depressive Symptoms

The Center for Epidemiologic Studies Depression Scale, the CES-D short form [72], was administered to the family member at baseline and follow-up to assess depressive symptomatology. This 10-item screening instrument with well-established psychometric properties measures the frequency of each depressive symptom in the past week on a scale from 0 (never or rarely) to 3 (every day). The possible range of scores is 0-30, with higher scores representing greater depressive symptomatology. A cut-off score of 10 or higher indicates the presence of significant depressive symptoms [72]. The Cronbach α for our family sample was 0.83.

Caregiver Appraisal Scale Outcomes

The Modified Caregiver Appraisal Scale [37] (CAS) was administered to family members at baseline and follow-up interviews. This 35-item multidimensional instrument assesses positive and negative appraisals of caregiving, based on the stress and appraisal framework [73]. It consists of 4 subscales, but only perceived burden and caregiver relationship satisfaction were

Table 1
Description of Veterans' In-home Program (VIP) Sessions

Session No.	Location	Persons Present	Activities
1	Home	Veteran, family	Introduce and provide overview of intervention: Manage problems with memory, organization, planning, or emotional functioning Remain independent in activities of daily living Make the home safer Use stress reduction techniques Discuss with veteran and family member what to expect at various stages of intervention. Provide overview of session goals Establish rapport with veteran and family Conduct clinical interview (review family's daily routines, preferences regarding veteran's interests). Confirm and discuss family constellation Begin assessment of veteran* (complementing prior OT assessments if done in clinic) Provide information and education materials about TBI and PTSD to veteran and family Obtain closure; review plan for next session Homework: The Pie of Life
2	Home	Veteran and family	Family Help family to understand the experience of recovery from the veteran's perspective Elicit family concerns Observe family's communication and interaction style Introduce and practice stress and emotional management techniques with family Veteran Complete assessments with veteran Conduct Allen Diagnostic Module (ADM2) Assess leisure interests Veteran and Family Member Introduce stress reduction techniques with veteran and family Obtain closure; review plan for next session Homework: Practice stress reduction techniques
3	Home	Family member	Provide overview of session goals Assess safety of home and elements of environment related to problem areas and strategies implemented. Assess elements of environment that support daily function and ability to navigate easily and safely through the home Reinforce stress management techniques with family member Identify and practice additional coping strategies to help family member take care of self Review assessment results with veteran and family Begin problem-solving process (ABC) and develop first action plan based on identified areas of need for veteran and family member and informed by clinical information Probe for additional problems Instruct family on specific communication approaches to support veteran's interpersonal skills and prevent emotional upset Veteran/family training may include: management strategies of behavioral and personality changes, task simplification, specific strategies reflecting modifications to the physical environment (home safety, adaptive equipment, de-cluttering, memory aids—external cues, other cognitive strategies) Summarize main session points; plan for next session
4	Phone	Veteran	Describe purpose of telephone contact Review identified problems and reinforce use of strategies developed in action plan; clarify action plan Validate veteran's actions in dealing with emotions and feelings Review the use of stress management techniques Reinforce integration of strategies into daily routines
5	Home	Veteran and family if possible	Provide overview of session goals with veteran and family member Reinforce stress management and coping techniques with family member Review progress in strategy use Reinforce and practice use of specific strategies Problem solve if unable to implement action plan and modify strategies as necessary Develop and practice second action plan Discuss generalization of strategies to other contexts (eg, within family, work, other community activities) Summarize main session points; plan for next session

(*continued on next page*)

Table 1 (*continued*)

Session No.	Location	Persons Present	Activities
6	Home	Family member	Review progress and reinforce strategy use with family member Reinforce and practice use of strategies Determine what was effective and modify strategies if necessary Discuss generalization of strategies to other contexts (eg, within family, work, other community activities) If relevant, introduce third action plan Provide recommendations for veteran's activity participation and community re-integration Summarize main session points; plan for next session
7	Telephone	Veteran	Review progress; clarify action plan(s) Reinforce use of strategies
8	Home	Veteran and family member	Reassess with COPM pre–post test Review all strategies and techniques used to address stated problem areas Discuss generalization to future circumstances Obtain closure Complete Readiness to Change Scale (for veteran and family member).

OT = occupational therapist; TBI = traumatic brain injury; PTSD = posttraumatic stress disorder; COPM = Canadian Occupational Performance Measure.

* Canadian Occupational Performance Measure, Allen Cognitive Level Scale–5, Toglia Cognitive Assessment.

selected as outcomes for family members in this study. Developed by Lawton et al [41], the CAS was later modified by Struchen et al [37], and tested in a sample of 214 family caregivers of adults with TBI. Evidence supports the tool's concurrent validity and good internal consistency for all subscales except mastery [37].

Caregiver Burden

Caregiver burden refers to the subjective perceptions of psychological distress, fatigue, anxiety, depression, poor health, social isolation, loss of freedom, feeling of being trapped, and resentment that are attributed directly to caregiving [37,41,42] for the veteran with TBI. Family members were asked to state their degree of agreement on a 5-point scale from 1 (strongly disagree) to 5 (strongly agree) to each statement, such as, "I feel isolated and alone as a result of caring for… [the veteran]," "I am very tired as a result of caring for…," and "My health has suffered because of the care I must give…" [37]. The Cronbach α in our sample of family members was 0.92.

Satisfaction With Caregiving

Measured by the Caregiver Relationship Satisfaction subscale, satisfaction with caregiving signifies positive appraisals—perceived gains from desirable aspects of caregiving and "uplifts," such as feelings of joy, pleasure, affirmation, or meaning experienced in caring for a family member [37,41,42]. It is measured with the same 5-point scale as the burden subscale. Examples of items include the following: "Helping this individual has made me feel closer to him or her," "This individual's pleasure over some little things gives me pleasure," and "The things I do for this individual keep him or her from getting worse." The Cronbach α in our sample was 0.83.

Veteran Clinical and Military Characteristics

Veteran data were retrieved from the VA Computerized Patient Record System (CPRS) regarding war cohort, TBI characteristics, and comorbidities. To determine TBI severity, a study co-investigator with expertise in rehabilitation medicine reviewed the subject's electronic medical record and determined the subject's severity level based on the VA/DoD Clinical Practice Guidelines [58,74].

Acceptability of VIP

Acceptability here refers to family members' engagement in the program and the feasibility of being able to deliver the program to them. Acceptability of the VIP was assessed through the following: scores on an acceptability tool that measured the family member's engagement in VIP and was completed by the interventionist after the final session; number of sessions attended; and willingness to participate in future studies on a similar topic. The 18-item acceptability tool has a 5-point Likert scale from 0 to 4, with higher scores indicating a more positive response [62,64,65]. The interventionists rated the family member on each item based on the referent, "Through the intervention overall, to what extent did the family members…?" Examples of items were as follows: "appear bored or uninterested?" "indicate the contact was useful?" "reject suggestions?" and "ask questions and demonstrate curiosity?" The Cronbach α for the sample was 0.88.

Procedure

Recruitment was conducted from March 2012 to February 2014, and follow-up ended in July 2014. Family members were interviewed at baseline and follow-up in their home on the same day as the veterans' interview. These interviews were conducted separately to ensure independent responses.

Data Analysis

Sample Description and Tests for Equivalence

Descriptive statistics characterized the sample on sociodemographics, TBI characteristics, and outcomes. Independent *t*-tests, χ^2, and Fisher exact tests were performed to assess for equivalence at baseline between family members in the intervention and control groups on sociodemographics, family outcome variables, and other measures not otherwise reported on in this article (rating of veterans' competency [75] and quality of relationship with the family member) [76].

Identification of Covariates

Associations of each of the 3 family outcomes with sociodemographic variations, years since injury, and injury severity were tested using Pearson product-moment correlations, independent *t*-tests, or χ^2 tests as appropriate.

Intervention Effects on Main Outcomes

Analyses of covariance (ANCOVAs) were conducted on each of the 3 family member outcomes (depressive symptoms, caregiver burden, caregiver satisfaction), using treatment assignment as the independent variable. Baseline values of each outcome and other variables, described in Results, served as covariates. Cohen *d* was determined as a measure of effect size [77]. Analyses were performed with SPSS, version 20 (IBM, Armonk, NY).

Results

Sample Characteristics

Baseline Equivalence Between the 2 Groups

Among 20 baseline comparisons with family members, only Hispanic ethnicity and financial difficulty were found to significantly differ, and were entered as covariates in subsequent analyses (Table 2).

Identification of Covariates

Associations of each of the 3 family outcomes (depressive symptoms, burden, and satisfaction) with sociodemographic variations (age, race, gender, years of education, financial difficulty, Hispanic ethnicity), years since last injury, and injury severity were tested using Pearson product-moment correlations, independent *t*-tests, or χ^2 tests as appropriate. Associations of outcomes with injury severity and with years since last injury were of particular interest in light of the wide range of each in the sample (mild to severe TBI and 1-45 years, respectively). Hispanic ethnicity was associated with higher caregiver burden scores (mean for Hispanics, mean = 3.21, SD = 0.83; for non-Hispanics, mean = 2.41, SD = 0.93, $t_{79} = 2.57$, $P = .012$). In addition, financial difficulty was associated with higher depressive symptomatology scores ($r = 0.335$, $P = .002$). These were used as covariates in the subsequent analyses. No other variables were significantly associated with the 3 family outcomes.

Family Members

Table 3 presents sociodemographic characteristics of the family members. Their mean age was 42 years. Almost 60% were white, and about 33% were black. Family members were predominately female and married. Most were spouses/partners of the veteran (73%), and about 15% were mothers. Sixty-three percent were employed, in contrast to about 35% of the veterans.

Veterans

Table 4 presents characteristics of veterans' TBI, war cohort, comorbidities, and major symptoms. Sources of the TBI varied, and more than one-third had experienced multiple TBIs (>4). About two-thirds had a mild TBI. Winter et al [58] present more information regarding the veteran sample.

Attrition Differences Between 2 Groups

No significant difference in drop-out (noncompletion of follow-up interview) was found between treatment and control: 34 of 40 (85.0%) in the Control condition completed the study versus 29 of 41 in the treatment condition (70.7%), $\chi^2(1) = 2.385$, $P = .123$. Family attrition was evident and was attributed primarily to scheduling difficulties for the follow-up interview.

Characteristics of Intervention

As VIP was designed, family members could participate in up to 6 home sessions. The large majority of sessions that included family members took place in the home (95.8%), and the remainder on the telephone.

Efficacy of Intervention

All 3 outcome variables—depressive symptoms, caregiver burden, and satisfaction with caregiving—had residuals (error terms) that were normally distributed. Levene test indicated that the assumption of homogeneity of error variances was met. Means and standard deviations (SDs) for baseline outcomes for the intervention and control groups are shown in Table 2. Table 5 shows the means and SDs for the 2 groups for each outcome measure at follow-up, ANCOVAs, and effect sizes. The ANCOVA for depressive symptoms showed a significant effect of the intervention, such that family members in the intervention condition had lower CES-D scores at follow-up than did control family members. The ANCOVA for caregiver burden showed that family members in the intervention condition had significantly

Table 2
Baseline (T1) differences between intervention and control groups in sociodemographic characteristics, baseline values of outcome variables, and other baselines values for family members (n = 81)

	Total	Intervention Group		Control Group					
Variable	Mean (SD) %	Mean (SD)	%	Mean (SD)	%	*t* (*df*)	χ^2 (*df*)	*P*	Mean Difference
Age, y	41.59 (12.51)	41.20 (12.14)		42.00 (13.02)		0.288 (79)		.774	0.805
Gender (% female)	93.8		92.7		95.0		1.88 (1)	.665	
Years of education	3.99 (1.03)	3.90 (0.89)		4.08 (1.16)			.751 (79)	.455	0.173
Years with partner	13.40 (11.40)	12.10 (9.99)		14.66 (12.64)		0.930 (67)		.356	2.554
Children (% with children)	82.7		85.4		80.0		0.408 (1)	.532	
No. of children	2.46 (1.44)	2.61 (1.44)		2.29 (1.45)		0.919 (68)		.362	−0.317
No. children at home	1.54 (1.18)	1.72 (0.94)		1.35 (1.37)		1.321 (68)		.191	−0.369
Employment (% employed)	63.0		61.0		65.0		0.141 (1)	.708	
Financial difficulty	1.38 (0.98)	1.66 (0.99)		1.10 (0.90)		2.654 (79)		.010	−0.559
Race (% nonwhite)	40.7		36.6		45.0		.594 (1)	.441	
Hispanic origin	12.3		4.9		20.0		Fisher exact test (1)	.039	
CES-D score	9.78 (6.16)	10.49 (6.68)		9.05 (5.57)		1.051 (79)		.297	−1.438
Quality of relationship	3.14 (0.53)	3.15 (0.49)		3.12 (0.57)		0.307 (79)		.760	−0.036
PCRS Interpersonal/social	3.15 (0.77)	3.15 (0.78)		3.14 (0.77)		0.054 (79)		.957	−0.010
PCRS cognitive	3.14 (0.99)	3.05 (1.00)		3.23 (0.99)		0.783 (79)		.436	0.173
PCRS physical	4.01 (0.73)	3.99 (0.78)		4.03 (0.68)		0.217 (79)		.829	0.035
Caregiver appraisal									
Burden	2.30 (1.05)	2.46 (0.94)		2.56 (0.97)		0.476 (79)		.636	0.101
Satisfaction	4.16 (0.67)	4.16 (0.77)		4.15 (0.55)		0.060 (79)		.952	−0.009
Ideology	3.40 (1.01)	3.41 (0.95)		3.40 (1.09)		0.087 (79)		.931	−0.020
Severity (% mild vs moderate to severe)			70.0 (mild)		68.3 (mild)		0.028 (1)	.868	
Time since most recent TBI	9.99 (11.12)	10.48 (11.30)			9.48 (11.15)	0.403 (79)		.688	−1.00

SD = standard deviation; CES-D = Center for Epidemiologic Studies Depression Scale, short form; PCRS = Patient Competency Rating Scale; TBI = traumatic brain injury.

Table 3
Characteristics of family members (n = 81)

	Mean (SD)	Range	% (n)
Age	41.59 (12.51)	21-67	
Gender (% female)			93.8 (76)
Marital status (% married)			84.0 (68)
Years married	13.40 (11.40)	1-41	
Have children			82.7 (67)
No. of children	2.46 (1.44)	0-7	
No. of children at home	1.54 (1.18)	0-5	
Financial well-being	1.38 (0.98)	0-3	
Employed			63.0 (51)
Race			
White			59.3 (48)
Black			32.1 (26)
Asian			3.7 (3)
No primary			2.5 (2)
Other			2.5 (2)
Hispanic/Latino			12.3 (10)
Relationship to veteran			
Spouse/partner			72.8 (59)
Mother			14.8 (12)
Sibling			4.9 (4)
Other			7.4 (6)

SD = standard deviation.

Table 4
Characteristics of veterans: Traumatic brain injury (TBI) severity, war cohort, source of TBI injuries, number of TBI-related events, comorbidity, and major symptoms (n = 81)

Characteristic	% (n) or Mean (SD)
Severity	
Mild	69.1 (56)
Mild-moderate	11.1 (9)
Moderate	11.1 (9)
Moderate-severe	3.7 (3)
Severe	4.9 (4)
War cohort*	
OIF (Iraq)	61.7 (50)
OEF (Afghanistan)	23.5 (19)
Both OIF and OEF	11.1 (9)
Dessert Storm (Persian Gulf)	6.2 (5)
Vietnam War	7.4 (6)
Post—Vietnam War era	9.9 (8)
Injury stateside (in U.S.)	4.9 (4)
Years since most recent TBI (mean/SD)	9.99 (11.17)
Source of TBI injury*	
Blast	55.8 (43)
Mechanical	24.7 (19)
Struck/thrown against object	19.7 (15)
Fall	31.2 (24)
Vehicular	33.8 (26)
Sports	8.6 (7)
Equipment malfunction	2.5 (2)
Assault/hazing by fellow service members	2.5 (2)
Other	8.6 (7)
Both blast and mechanical	32.1 (26)
No. of TBI-related incidents	
1	29.6 (24)
2	16.0 (13)
3	6.2 (5)
4	4.9 (4)
>4	37.0 (30)
Unknown	6.2 (5)
PTSD diagnosis during study period	66.7 (54)
Depression diagnosis during study period	61.0 (47)
Frequency of TBI-related symptoms*	
Pain	71.4 (55)
Tinnitus	25.9 (21)
Photosensitivity	22.1 (17)

SD = standard deviation; OIF = Operation Iraqi Freedom; OEF = Operation Enduring Freedom; PTSD = posttraumatic stress disorder.
* Does not add to 100% because some were in more than 1 category

lower burden scores at follow-up compared to control-condition family members. Only caregiver satisfaction did not show a significant effect for the intervention.

Acceptability of Intervention

Of the 40 veterans/family dyads randomized to intervention, 37 (92.5%) were willing to participate. Family members participated in a mean of 4.67 sessions, among a possible 6, representing 78% of maximum possible participation. The mean acceptability score (possible range 0-4) was 2.67 (SD = 0.73). Furthermore, 85.5% of family members answered that they would be willing to participate in another study on the same topic [TBI]. These data indicate that the VIP was acceptable to families.

Discussion

At follow-up, family members who received the VIP intervention showed significantly lower depressive symptom scores and caregiver burden scores than control-condition family members. Caregiver satisfaction did not differ between the 2 groups. As reported in the study of veteran outcomes by Winter et al [58], veterans in the VIP also showed benefits—significantly higher community reintegration and better ability to manage patient-identified targeted outcomes overall—compared to veterans in the control. To our knowledge, this is the first randomized controlled trial to document beneficial effects of an intervention for both the veteran with TBI and the veteran's family member. In addition, VIP was acceptable to both family members and veterans [58].

Our intervention showed a benefit for the 2 most common psychosocial problems reported by family caregivers—depression and burden [28]. Because depression may influence everyday functioning, quality of life, relationships, and work [78-80], an intervention that reduces depressive symptoms has the potential to make a difference in the lives of family members. The mean depression score for family members in VIP at follow-up was 9.03 (SD = 6.46), compared to 10.74 (SD = 7.40) in control family members. This suggests a clinically as well as statistically significant change, because a depression score of 10 or higher indicates significant depressive symptomatology [72].

Table 5

Analysis of covariance results and Cohen *d* for family members' outcomes, adjusting for Hispanic ethnicity, financial difficulty, and baseline values of outcome variable

Outcome	Intx mean (SD)	Control mean (SD)	F (*df*)	*P*	Cohen *d*
Depressive symptoms	9.03 (6.46)	10.74 (7.40)	10.55(1,58)	.002	.244
Burden	2.12 (0.97)	2.45 (1.10)	5.90 (1,58)	.018	.311
Satisfaction	4.25 (0.61)	4.24 (0.61)	.308 (1,58)	.581	.01

SD = standard deviation, Intx = Intervention.

Caregiver burden represents a multidimensional subjective response to the varied stressors associated with caregiving [37,41]. Because caregiver burden encompasses subjective perceptions of many domains, such as anxiety, fatigue, depression, poor health, and resentment attributed to caregiving [37], the significant effect of VIP on caregiver burden suggests that the intervention had a broad impact on biopsychosocial domains.

Our findings of reduced depression and burden in veterans' family members are also clinically compelling, given that some families may be considered at higher risk for negative outcomes because of prolonged stress. Some families in our sample may have already been stressed from multiple and extended deployments before the veteran's return home [45]. Moreover, many families and veterans in our sample were concurrently dealing with other physical comorbidities (eg, chronic pain) and psychological comorbidities (depression, PTSD) present in the veteran that interact with TBI symptoms [45].

In previous research, a reduction in depressive symptoms has also been achieved with problem-solving interventions, such as the in-home intervention with family caregivers in Rivera et al's study [52]. The protocol for VIP is similar to that of Rivera et al, as their protocol involved identifying the problems most pressing to caregivers, choosing solutions, implementing them, and evaluating them. Positive effects of problem-solving training (PST) have also been seen in family caregivers of persons with stroke and spinal cord injury [81-83]. Furthermore, problem-solving self-appraisal has been positively correlated with interpersonal skills needed for community reintegration in persons with TBI [84], mirroring the finding by Winter et al [58] that VIP improved veterans' community reintegration. Taken together, these findings suggest that problem-solving on issues of most concern to adults with TBI and their families is a promising approach. Adding further support for this approach are positive study outcomes reported in family members of children with TBI who received family problem-solving interventions via telehealth [85].

PST training in the study by Rivera et al [52] was delivered to caregivers in the home to minimize problems with "mobility, isolation, and access, which typically limit services to caregivers" (p. 3). Although we did not compare our home-based VIP with a clinic-based program, we speculate that the in-home sessions of VIP may have increased access to services for veterans with TBI and their families—particularly important now as the VA confronts serious problems in veterans' access to care [86,87].

Caregiver satisfaction did not differ between intervention and control groups at follow-up. Satisfaction, which reflects positive feelings such as joy and pleasure experienced in caring for a family member [37,41], may be a more complex dimension for family members of TBI patients and may require different types of intervention. However, satisfaction scores in both the intervention and control groups were relatively high at baseline (>4 on a range of 1-5), possibly making it more difficult to improve satisfaction through the intervention. Given that satisfaction represents a positive appraisal of caregiving, it is interesting that higher baseline satisfaction was observed even in the presence of the higher level of baseline depressive symptoms seen in our sample of family members.

Despite the absence of a treatment effect for satisfaction in our family member sample, future research should continue to tease out the role of positive aspects of caregiving, such as satisfaction, in varied family and patient outcomes after TBI. For example, positive caregiving experiences may contribute to more a positive relationship with the person with TBI, which may in turn lead to better rehabilitation outcomes. Exploration of outcomes from positive caregiving experiences and factors related to these positive experiences (eg, demographics, caregiver mental health, and TBI characteristics) is an emerging line of inquiry that will advance understanding of the full range of caregiving experiences [88].

Arranging home visits at times when both veterans and family members were present was challenging due to busy schedules and family members' employment. Nevertheless, family members attended the large majority of home visits available to them and experienced direct benefits of the intervention. From a family systems perspective [89], it is plausible that veterans' benefits from the intervention (increased community reintegration and ability to manage TBI-related problems) [58] may have had an indirect effect on family member burden and depression, perhaps by enabling family members to increase their own social activities and social support. The interrelationships among family and veteran outcomes are complex and often not addressed in family intervention studies in general, thus reinforcing the need for examination in future research. For example, possible mediation of the intervention effect for family members by veterans' benefits from the intervention is an important topic for future study.

Our study findings must be considered in light of several limitations. First, findings can be generalized only to family members of veterans with TBI who receive diagnoses and are offered services within a Veterans Health Administration (VHA) polytrauma program, and may not be applicable to family members of non-VHA users and civilians with TBI. Veterans with TBI within the VHA system of care may have comorbidities (eg, more PTSD and depression) that present a different clinical picture compared to veterans with TBI who are receiving private care or civilians with TBI. About 40% of veterans who served in OEF, OIF, or Operation New Dawn have not used VA health care since October 2001 [90], and their families may differ from families of those who use VHA services. Given the mean time of 10 years since the last TBI in the veteran sample and the wide range of years since the last TBI, our findings also may not be applicable to families of non-VA populations whose TBIs are more recent. Future research should replicate this study with larger samples that include veterans and civilians who have experienced TBI at varied times in the past and their family members, including veterans with TBI from non-VHA settings and civilians with TBI. If future studies confirm the impact of VIP on non-VHA populations, that would argue for the transferability of the approach and would support reimbursement models that treat family members as part of the system of care for TBI.

Another limitation is the absence of long-term follow-up in our study, which may be addressed through extended longitudinal designs. In light of the attrition rate among family members in our sample, future studies should implement retention strategies and more flexible scheduling to decrease family attrition. Finally, it is possible but improbable that intervention effects were due to the intervention group simply having more contact with the study team than the control group.

Representing the first evidence-based intervention demonstrating significant effects for both the veteran with TBI [58] and the family, the VIP is an important step toward filling a critical gap in service provided by the VHA polytrauma program nationwide. The VHA's priorities now include greater attention to the well-being of family members [91,92], who both need help and provide essential support for patients with TBI. VIP is an evidence-based intervention that can be translated into current VHA practice, with meaningful benefits for veterans with TBI and their families. As the VHA systematically evolves to adopt a more family-centered approach to care [91,92], this study supports reinforcement of such efforts.

Conclusion

VIP is a promising approach to support families of veterans with TBI. Its acceptability for families in our sample was high, and delivery of this program in the home may improve access to services—a critical issue with TBI in particular [52] and the VHA in general [86,87]. With study refinement and replication in military and civilian samples, an in-home service such as VIP may be an optimal approach to engaging and assisting families of persons with TBI.

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